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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,425	06/20/2005	Hans List	21690 US-dc	8024

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ROCHE DIAGNOSTICS OPERATIONS INC.  
9115 Hague Road  
Indianapolis, IN 46250-0457

EXAMINER
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WHITE, DENNIS MICHAEL

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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05/18/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

karla.dirks@roche.com  
marsha.breen@roche.com  
michele.wilson@roche.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,425	<b>Applicant(s)</b> LIST ET AL.	
	<b>Examiner</b> DENNIS M. WHITE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Amendments filed on 5/11/2009 have been noted. Claims 18-33 were cancelled. Currently claims 1-17 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al (USP 4,163,643).

Regarding claims 1-2 and 17, Hunter et al teach a discrete sample analysis apparatus ("detecting unit") comprising a piezoelectric vibratory conveyer ("transport unit comprises at least one piezoelectric element") (col. 2 lines 18, col. 5 lines 43, col. 12 lines 28-30 and claim 6) to convey samples in a tube ("test element") comprising a collar section 97 ("carrier") and lower section 97 to contain the sample ("evaluation area") to detectors 58 and 59 ("detector") (col. 5 lines 1-10, Fig. 3: 58 and 59). Computing equipment ("evaluation unit") is used to take the measured data and calculate the concentration of the antigen. The transport of the tube is formed to be arrested ("stopped") when at detectors 58 and 59 (col. 2 lines 55-60).

Regarding claim 3, Hunter et al teach the tubes present in a sample store module 23 ("magazine housing") (col. 7 lines 45-64).

Regarding claim 4, Hunter et al teach the detectors are along the vibratory track (Fig. 3: track near detectors 58 and 59).

Regarding claim 5, Hunter et al teach the piezoelectric drive vibrating the stack of spiral units independently (“at least two piezoelectric elements that are electronically actuated independently of one another”) (col. 5 lines 40-48, col. 12 lines 18-31).

Regarding claims 6-8, Hunter et al teach the piezoelectric element is controlled (“detector” is read on controller because it is used “to control”) separately by the electrical input from the apparatus (“detection unit”) (col. 9 lines 13-27). The same controller (“detector”) initiates the detection of the sample in the tube (“detector detects the evaluation area of a test element”).

Regarding claim 9, Hunter et al teach the collar of the tube is in contact with the track (“contact area of the transport unit and the carrier of the test element are made such that in a resting state of the transport unit static frictional forces act between the contact area and the carrier to such an extent that the test element is fixed in position relative to the transport unit”) (Fig. 10: M and D).

Regarding claim 10, Hunter et al teach a gate mechanism (“contact sensor”) which allows for transport (“activates the transport unit”) of the tube, which is in contact with the track (“when the test element contacts the contact area of the transport unit”).

Regarding claim 11-12, Hunter et al teach the transport unit is arranged on a vertical pillar 118 which allows the spiral units to undergo torsional oscillation (“rotation”). The pillar is fully capable for bearing and positioning a reel and a test strip tape wound onto a reel.

Regarding claim 13-14, and 16, Hunter et al teach a method for transporting a tube (“test element”) in an analytical system comprising contacting a tube (“test

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element”) directly with a contact area of a vibratory piezoelectric transport unit in an analytical system, and prior thereto activating a piezoelectric element of the transport unit such that the contact area of the transport unit is vibrated, transporting the test element due to the vibrated contact area along a predetermined transport path in the analytical system and stopping the transport process of the tube (“test element”) such that the test element is positioned at detectors 58 and 59 (“predetermined site in the analytical system” “detection site” “detection unit for detecting at least one signal changed by an analyte”) (col. 12 lines 18-31). The computing equipment (“evaluation unit”) is used to take the measured data and calculate the concentration of the antigen (“determine at least one analyte in the sample based on the at least one signal”)

Regarding claim 15, Hunter et al teach the tube is placed in a storage module 23 (“test element is returned into a magazine”).

4. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishizaka et al (USP 5,077,010) in view of Kitamoto et al (USP 4,875,610).

Regarding claim 1, 13-14, 16-17, Ishizaka et al teach biochemical analysis apparatus and method (“analytical system for determining an analyte in a sample”) comprising providing a measuring device for measuring the optical density produced by a color reaction of a long test film 3 (“a detection unit for detecting at least one signal that has been changed by an analyte in a sample”) and the measurement results are fed to a computer 20 (“evaluation unit to determine at least one analyte in the sample based on the at least one signal”) and a motor to rotate a drive a reel of the long test film (“transport unit with a contact area wherein the contact area is suitable for directly

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or indirectly contacting the analytical system with a test element on which the sample can be applied” “for transporting a test element in an analytical system comprising contacting a test element directly or indirectly with a contact area of a transport unit in an analytical system”). The test film (“test element”) is transported along a defined transport path in the analytical system as soon as the contact area of the transport unit is directly or indirectly contacted with a test element. The test film is mounted on a cassette like those used in audio and video cassette tapes (col. 22 lines 42-51, col. 35 lines 35-54). Ishizaka teach the method further comprising sample application, incubation, and measurement is carried out at a single position (“stopping of the transport process of the test element such that the test element is positioned at a predetermined site in the analytical system” “positioned relative to a detection site of a detection unit of the analytical system”) (col. 11 line 56-col. 12 line 9).

Ishizaka et al is silent that the transport unit comprises at least one piezoelectric element which vibrates the contact area of the transport unit.

Kitamoto et al teach a method and system for driving tape in a cassette comprising a piezoelectric elements 1 and 2 to produce an ultrasonic oscillations to advance the tape (“activating a piezoelectric element of the transport unit such that the contact area of the transport unit is vibrated, transporting the test element due to the vibrated contact area along a predetermined transport path in the analytical system”). It is advantageous to use this driving system in order to overcome the tape meandering, twisting or being stretched by tension of the conventional capstan and pinch roller.

It would have been obvious to one of ordinary skill in the art to substitute the motor of Ishizaka et al with the piezoelectric elements of Kitamoto et al in order to provide a driving means that advances the tape without meandering, twisting or being stretched by tension caused by conventional rotating motors.

Regarding claim 2, Ishizaka/Kitamoto teach a test film 210 with a support 211 and an analysis region 214 (“the test element wherein the test element comprises a carrier and an evaluation area on which the sample is applied”).

Regarding claim 3, Ishizaka/Kitamoto teach the test film is in a cassette 1 (“test element is present in a magazine housing”).

Regarding claim 4, Ishizaka/Kitamoto teach a detection site is located in the analytical system along the transport path (Fig. 4: 57).

Regarding claim 5, Ishizaka/Kitamoto teach two piezoelectric elements 1 and 2 can comprise a piezoelectric element pairs, each pair comprising first and second piezoelectric elements 11 and 12. These elements alternate with each other from alternating electric sources Ea and Eb (“that are electronically actuated independently of one another”) in order to create a traveling wave (Kitamoto: col. 2 line 57-col. 3 line 9).

Regarding claim 6 and 10, Ishizaka/Kitamoto teach in which the driving means such as the piezoelectric element is controlled by a tape position detecting means (“detector” “contact sensor which activates the transport unit when the test element contacts the contact area of the transport unit”); (Ishizaka: Fig. 4: 56 “photoelectric switch”, col. 12 lines 9-39; Kitamoto: col. 4 line 59-col. 5 line 6).

Regarding claim 7, Ishizaka/Kitamoto teach the detector is a component of the detection unit (Fig. 4: 55-57).

Regarding claim 8, Ishizaka/Kitamoto teach the detector detects holes or markings on the evaluation area of a test film ("element") (Ishizaka: col. 12 lines 9-39).

Regarding claim 9, Ishizaka/Kitamoto teach the contact area of the piezoelectric elements ("transport unit") and the test film support ("carrier of the test element") are made such that in a resting state of the transport unit static frictional forces act between the contact area and the carrier to such an extent that the test element is fixed in position relative to the transport unit.

Regarding claim 11, Ishizaka/Kitamoto teach a reel 6 is mounted on a rotatable shaft ("a carrier element to rotate" "which is suitable for bearing and positioning a reel"). The shaft is fully capable of being rotated by the piezoelectric elements because the tape would be advanced causing the reel to rotate and thus the shaft to rotate.

Regarding claim 12, Ishizaka/Kitamoto teach the use of long test film on a reel ("which is suitable for using a test strip tape wound onto the reel").

Regarding claim 15, Ishizaka/Kitamoto teach the step wherein the test film ("element") is returned into a used film cassette part 2 ("test element is returned into a magazine").

### ***Response to Arguments***

5. Applicant's arguments filed on 5/11/2009 have been fully considered but they are not persuasive.



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6. Applicants argue that Hunter does not teach a piezoelectric element. It is noted that Hunter does teach a piezoelectric element (col. 2 lines 18, col. 5 lines 43, col. 12 lines 28-30 and claim 6). Therefore Hunter meets the claimed limitations.

7. Applicants argue that the Kitamoto reference relates to a different technical field which is wholly unrelated to Applicants claimed analytical systems and methods. In response to applicant's argument that Kitamoto is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Ishizaka and Kitamoto are directed at the particular problem with which the applicant was concerned specifically for the driving of tape. Furthermore Ishizaka teach the motivation that the test film is mounted on a cassette like those used in audio and video cassette tapes and is therefore directed to the problem of moving tape in a cassette. Therefore the combination is considered proper.

### ***Conclusion***

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Lyle A Alexander/

Primary Examiner, Art Unit 1797

/dmw/